# CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE Minutes – Regular Meeting Tuesday – August 20, 2013

A regular meeting of the Connecticut Stem Cell Research Advisory Committee "Advisory Committee" was held on Tuesday, August 20, 2013, at the offices of Connecticut Innovations, 865 Brook Street, Rocky Hill, Connecticut.

<u>Call to Order</u>: Noting the presence of a quorum, Marianne Horn, representing Jewel Mullen, Chairperson of the Advisory Committee and Commissioner of the Department of Public Health, called the meeting to order at 1:04 p.m. Members present: Richard H. Dees, Ph.D. (by phone); Sandra Engle, Ph.D. (by phone); Gerald Fishbone, M.D; David Goldhamer, Ph.D.; Marianne Horn, J.D., representing Jewel Mullen, M.D., M.P.H., M.P.A.; James Hughes, Ph.D. (by phone); Diane Krause, M.D., Ph.D. (by phone); and Milton B. Wallack, D.D.S.

Members absent: Treena Livingston Arinzeh, Ph.D; Ronald Hart, Ph.D.; Ann Kiessling, Ph.D; and Paul Pescatello, J.D., Ph.D.

<u>Other Attendees</u>: Cheryl Allevo (CI); Isolde Bates (UCONN); Terri Clark (CASE); Joseph Landry (CI); Claire Leonardi (CI); Rick Strauss (CASE); and Paula Wilson (YALE) (by phone).

## **Opening Remarks**

Attorney Horn welcomed everyone and noted that she has been designated by Dr. Mullen to chair the meeting in her absence.

Attorney Horn thanked Ms. Allevo for her service to the Advisory Committee and wished her luck in her future endeavors.

# Approval of Minutes – Advisory Committee Meetings

The Advisory Committee members were asked to consider the minutes from the July 16, 2013 meeting.

MOTION: Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the Advisory Committee members voted in favor of adopting the minutes from the July 16, 2013 regular meeting with the following corrections made (page 8, change the word "accepting" in the first motion to "accepted," and page 6, change "Ms. Krause" to "Dr. Krause." VOTE: 8-0-0 (In favor: Dees, Engle, Fishbone, Goldhamer, Horn, Hughes, Krause, and Wallack) MOTION PASSED.

## **Myron Genel Resignation**

Attorney Horn noted that a copy of the letter that was sent to Dr. Genel on behalf of the Stem Cell Research Advisory Committee was included in the package. Attorney Horn should be contacted with recommendations on Advisory Committee appointments.

#### Carryover Requests for 2012 Awards

Mr. Landry discussed an issue that was brought to his attention about a potential financial gap as a result of the timing of submission of reports and carryover requests, if applicable, and approval by the Advisory Committee. He spoke about some of the issues that have caused delays in the past (i.e. correction of lay summaries, cancelation of meetings). There was a discussion about the reporting requirements for the different funding years and how to alleviate the financial funding gap encountered by Yale. Ms. Bates explained the process used by UCONN to process grants from year to year. A suggestion was made to authorize a determined about to be carried forward without requiring prior approval from the Advisory Committee.

Sections 8 and 9 of the Financial Assistance Agreement regarding reallocation of budgets was reviewed and discussed by the Advisory Committee members. It was determined that carryover requests can be treated like budget reallocations to be approved as specified in the Financial Assistance Agreement using the Carryover Request Form.

#### Final Reports—Technical and Financial

The Advisory Committee members reviewed the final technical and financial reports for the following grants:

- 10-SCA-22, Dr. Rodeheffer (Yale), principal investigator
- 08-SCB-UCHC-011, Dr. Zecevic, principal investigator
- 09-SCD-UCHC-01, Dr. Xu, principal investigator and subreport from Dr. Grabel (Wesleyan).

<u>MOTION:</u> Upon a motion made by Dr. Dees, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of accepting the final reports for grant 10-SCA-22, Dr. Rodeheffer, principal investigator. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Goldhamer, Horn, Hughes, and Wallack; Abstention: Krause) **MOTION PASSED**.

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Krause, the Advisory Committee members voted in favor of accepting the final reports for grant 08-SCB-UCHC-011, Dr. Zecevic, principal investigator. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Horn, Hughes, Krause, and Wallack; Abstention: Goldhamer) MOTION PASSED.

Ms. Allevo was asked to send a copy of the subreport from Dr. Grabel to the Advisory Committee members.

<u>MOTION:</u> Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of accepting the final reports for grant 09-SCD-UCHC-01, Dr. Xu, principal investigator. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Horn, Hughes, Krause, and Wallack; Abstention: Goldhamer) **MOTION PASSED**.

## Change in Pl

The Advisory Committee members discussed the request for a change in principal investigator for grant 12-SCA-UCHC-15, from Dr. Carlson to Dr. Kuchel.

**MOTION:** Upon a motion made by Dr. Krause, seconded by Dr. Wallack, the Advisory Committee members voted in favor of approving the change in principal investigator for grant 12-SCA-UCHC-15, from Dr. Carlson to Dr. Kuchel. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Horn, Hughes, Krause, and Wallack; Abstention: Goldhamer) **MOTION PASSED**.

#### **Revised Lay Summaries:**

The Advisory Committee members reviewed the revised lay summaries for the following grants:

- 10-SCA-38, Dr. Qiu (Yale), principal investigator
- 10-SCA-13, Dr. Cheng (Yale), principal investigator
- 11-SCD-02, Dr. Lin (Yale), principal investigator
- 10-SCA-18, Dr. Wells (Yale), principal investigator

**MOTION:** Upon a motion made by Dr. Dees, seconded by Dr. Wallack, the Advisory Committee members voted in favor of accepting the revised lay summaries and final reports for the following grants:

- 10-SCA-38, Dr. Qiu (Yale), principal investigator
- 10-SCA-13, Dr. Cheng (Yale), principal investigator
- 11-SCD-02, Dr. Lin (Yale), principal investigator
- 10-SCA-18, Dr. Wells (Yale), principal investigator

VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Goldhamer, Horn, Hughes, and Wallack; Abstention: Krause) **MOTION PASSED**.

#### **Revised Budgets for 2013 Awards**

Mr. Landry explained that at the June 2013 grant review meeting, several grants were approved at reduced amounts, subject to approval of the revised budgets. The Advisory Committee members discussed the revised budgets for grants 13-SCDIS-ISB-01, Dr. Xu, principal investigator, and 13-SCB-Yale-12, Dr. Xiao. A comment was made that the summary for one of the revised budgets indicates that the aims of the project would not be impacted by the reduction in the budget, and the principal investigator may not have needed the full amount when the application was filed. A suggestion was made to consider adjusting the maximum funding amounts for each of the grant categories when considering the Request for Proposals ("RFP") for the 2014 funding round. Questions arose as to how the aims and outcomes would be changed as a result of the budget reduction for the grants. Mr. Landry read the letter that was sent to the grant awardees asking for a revised budget. He noted that the letter specifically requests a revised budget showing how all of the work in the grant application can be performed with less funding. A suggestion was made to approve the revised budgets but to give the principal investigators the option to revise the goals or to explain what can or cannot be achieved with the reduced funding. Some concern was expressed with giving the option to revise the goals because the proposal presented was the proposal reviewed by the peer reviewers.

CI was asked to check the revised budget for grant 13-SCDIS-ISB-01, Dr. Xu, to ensure that the numbers for indirect costs add up correctly.

**MOTION:** Upon a motion made by Dr. Krause, seconded by Dr. Wallack, the Advisory Committee members voted in favor of accepting the revised budget for grant 13-SCDIS-ISB-01, Dr. Xu, principal investigator. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Horn, Hughes, Krause, and Wallack; Abstention: Goldhamer) **MOTION PASSED**.

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of

accepting the revised budget, subject to the final indirect costs being verified and approved by CI for grant 13-SCB-YALE-12, Dr. Xiao, principal investigator. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Goldhamer, Horn, Hughes, and Wallack; Abstention: Krause) **MOTION PASSED**.

The Advisory Committee members were asked to consider changing the order of the agenda.

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Goldhamer, the Advisory Committee members voted unanimously in favor of changing the order of the agenda to discuss revisions to the 2014 RFP before the next agenda item. VOTE: 8-0-0 (In favor: Dees, Engle, Fishbone, Goldhamer, Horn, Hughes, Krause, and Wallack **MOTION PASSED**.

## Revisions to 2014 Request for Proposals ("RFP")

Attorney Horn reviewed the proposed changes to the 2014 RFP, noting that comments received over the last several months have been incorporated and/or highlighted for further discussion by the Advisory Committee members.

A question arose as to whether there is language in the RFP under the selection criteria about giving preference to principal investigators who do not already have or have not in the past received funding from the State of Connecticut for stem cell research. In an effort to be as transparent and clear as possible, a suggestion was made to include language that indicates that established investigators who have two or more active concurrent grants may not be considered or given as high a priority in the current funding round. In response to a question, it was noted that the National Institutes of Health ("NIH") does not have a policy like this. A comment was made that one of the main focus for Connecticut is to foster a stem cell community and providing funding to the same principal investigators is contrary to that focus, and established investigators should be encouraged to seek other funding.

A discussion ensued on the due date for applications, and Mr. Strauss explained the rationale for the proposed dates. Ms. Leonardi discussed the "lean process" being developed between CI, DPH and CASE to streamline the entire administrative process for proposals.

The date on page 5 will be changed to July "2014."

The Advisory Committee members discussed funding for Core proposals. Several Advisory Committee members expressed the desire to move the Core proposals towards self-funding and to reduce funding for the 2014 funding year. If the Advisory Committee is considering reduced funding for the cores, a suggestion was

made to invite the principal investigators of the core facilities to the next Advisory Committee meeting to explain the progress each of the core facilities has made to become self-sustaining. There was a discussion on a potential amount to reduce funding for Cores facilities for 2014. A suggestion was made to reduce funding by one-half, but several members were opposed to such a large reduction. Another suggestion was made to reduce total funding of cores to \$800,000 rather than \$1,000,000 for 2014. A discussion ensued on potential ways for the Cores to raise funding and eventually become self-sustaining.

Ms. Bates indicated that UCONN is having a departmental review on September 17, the date of the next Advisory Committee meeting, and all faculty is required to attend; therefore, Dr. Lalande will not be available to make a presentation at the September 17 Advisory Committee meeting. There was general consensus that the RFP has to be finalized by the end of the September 17 meeting and to allow Dr. Lalande to send a designee or to send something in writing to the Advisory Committee meeting. Attorney Horn and/or Ms. Leonardi were asked to personally invite the principal investigators of the cores to the September 17 Advisory Committee meeting.

There was a discussion about potentially reducing funding for specific grant categories. The Advisory Committee members considered funding for Disease Directed Collaboration Group Projects and Group Projects. Several suggestions were made (reduce Group Projects to \$1,250,000 and/or reduce the length of time the proposals are funded to three years rather than four). After a discussion, there was general consensus that both Disease Directed Collaboration Group Projects and Group Projects should be funded at the same level and a maximum of \$1,500,000 for each proposal. After discussion of the funding level for Established Investigators, there was general consensus that \$750,000 is an appropriate cap for the category.

A suggestion was made to be more specific in the RFP about expectations regarding lay summaries. The lay summaries should include an explanation of the progress made, difficulties encountered, and the final results should be written for understanding by the general public, the Advisory Committee and for publication on the Web.

A suggestion was made to consider in the future a registry of scientists in the state to help provide an understanding of what is being done in the state with stem cell research and to help with collaboration issues.

The Advisory Committee members discussed the usefulness of having the applicants identify whether the current proposal is a resubmission of a previous grant application; and if so, briefly (one to two pages) explain how the proposal was revised to the current submission.

The Advisory Committee members were asked to provide Attorney Horn with any additional comments before the September 17 meeting.

#### **Change in Scope and Rebudget Request**

Mr. Landry asked the Advisory Committee members for input on the request received from Dr. Qyang, principal investigator for grant 12-SCB-YALE-06 to change the scope of the project. Dr. Qyang has indicated that a portion of the project is "within the fundable range" for an NIH grant. A discussion ensued on how to proceed. Based on the information provided by Dr. Qyang, it appears that aim 2 is substantially the same as the aim anticipated to be funded by NIH. The Advisory Committee members expressed the need for further clarification about the overlap of the project that is anticipated to be funded with NIH funds, and a more detailed revised budget without the overlapped portion should be provided.

**MOTION:** Upon a motion made by Dr. Engle, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of tabling the request for a change in scope for grant 12-SCB-YALE-06, Dr. Qyang, principal investigator, until further clarification is provided on the overlap of the project with the project that is anticipated to be funded with NIH funds and a more detailed reduced budget is provided. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Goldhamer, Horn, Hughes, and Wallack; Abstention: Krause) **MOTION PASSED**.

## **No-Cost Extension**

Mr. Landry explained the request for a no cost extension for grant 10-SCB-02, Dr. Rizzolo, principal investigator, through June 30, 2014.

<u>MOTION:</u> Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of approving the no-cost extension for grant 10-SCB-02, Dr. Rizzolo, through June 30, 2014. VOTE: 7-0-1 (In favor: Dees, Engle, Fishbone, Goldhamer, Horn, Hughes, and Wallack; Abstention: Krause) **MOTION PASSED**.

## **Yale Refund Request**

Mr. Landry explained that at the July meeting, the Advisory Committee members voted to table the action with respect to a refund for grant 06-SCE-01, Dr. Lin, principal investigator, until further clarification is provided. Mr. Landry mentioned that a response from the principal investigator is expected in September.

## **Rebudget Grant Awards**

Mr. Landry reviewed the rebudget requests approved by CI, which include:

- 12-SCB-Yale-01, Dr. Horsley
- 11-SCA-10, Dr. Martins-Taylor

#### **Public Comments**

Mr. Strauss commented on the process for approving the second year of funding for two-year grants. He suggested that the Advisory Committee consider another approach for future rounds such as allowing budgets based on a two-year basis rather than annual basis and holding back a certain percentage (i.e. 20 percent), to be released following approval of an annual report.

Mr. Strauss indicated the importance of meeting with the principal investigators of the cores and suggested that a special meeting be scheduled on a date that is mutually convenient rather than having a meeting on a date when one of the principal investigators cannot attend.

Mr. Strauss spoke about the need to consider legislation that authorizes some administrative support and the continuance of the Stem Cell Research Advisory Committee in the event funding does not get extended.

With respect to the RFP for the 2014 grant round, Mr. Strauss suggested using a link for the NIH guidelines that are referenced in the document.

Mr. Strauss questioned how the selection criteria are used by the Advisory Committee members to make decisions on the grant proposals and noted how the vagueness can raise questions by the applicants and public. He suggested that the Advisory Committee continuously look at the process and determine how to make improvements.

#### **Next Meeting Date**

The next meeting will be held on September 17, 2013.

## **Adjournment**

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of adjourning the meeting at 4:00 p.m.

Respectfully submitted:
Dr. Jewel Mullen, Chair